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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,178	04/27/2007	John Ross Hawkins	IP21L10.001APC	8937

20995 7590 03/24/2010
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EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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03/24/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/582,178	Applicant(s) HAWKINS, JOHN ROSS	
	Examiner Michael C. Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-22-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-10, in the reply filed on 12-15-09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 10 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12-15-09.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Fournier (US Patent 5,543,319).

Fournier taught intact human chromosome 22 cloned into the chicken B-cell line DT40 (col. 8-11; see col. 8, Example 2; col. 9, Example 4 and col. 11, Example 5, which discloses integration of human chromosome 11 into the chicken ovalbumin locus in

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DR40 cells; col. 8, line 66, states the chromosome was intact). The chromosome is a "human genetic reference sequence" as in claim 1. The human chromosome was integrated into the chicken ovalbumin locus, which is equivalent to "cloned into a dispensable region of the cell's genome" in claim 6 because the cell can survive.

The patent office does not have the ability to determine whether the chromosome was integrated into a "non-expressed region of the cells" as in claim 7. Therefore, without evidence to the contrary, the chromosome was integrated into a "non-expressed region of the cells" as in claim 7 because the LIF locus comprises more "non-expressed" than "expressed" regions.

Claims 8 and 9 have been included in view of the paragraph bridging pg 13-14 of the specification, which states: "Following recombination after introduction of the plasmid 14 into the host cells 11, three cell types may be present. Cell type 17 represents a hemizygote containing the integrated human genetic reference sequence 16 and the antibiotic resistance marker 15 flanked by the two mutant LoxP sites 7 and 8. There may also be cells 18 homozygotic for the human genetic reference sequence 16, the antibiotic resistance marker 15 and the two mutant LoxP sites 7 and 8. Finally, there will be a population of cells 19 that has not been 5 transformed. [underlining added]" The method of Fournier inherently results in some cells homozygous for the transgene because it is the same method used by applicants – homologous recombination – described by applicants as achieving homozygosity. It is noted that the paragraph bridging pg 13-14 is part of Embodiment 2, which "demonstrates how the invention may be worked to create a di-allelic genetic reference standard" which is

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equivalent to "diploid" in claim 8 and "a plurality of human genetic reference sequences" in claim 9.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuroiwa (Nucleic Acids Res., 1998, Vol. 26, No. 14, pg 3447-3448).

Kuroiwa taught a truncated human chromosome cloned into the chicken B-cell line DT40. The chromosome is a "human genetic reference sequence" as in claim 1.

The human telomeric repeat was integrated into the LIF locus at 22q12 just distal to the Igλ, which is equivalent to "cloned into a dispensable region of the cell's genome" in claim 6 because the cell can survive without LIF.

The patent office does not have the ability to determine whether the chromosome was integrated into a "non-expressed region of the cells" as in claim 7. Therefore, without evidence to the contrary, the chromosome was integrated into a "non-expressed region of the cells" as in claim 7 because the LIF locus comprises more "non-expressed" than "expressed" regions.

Claims 8 and 9 have been included in view of the paragraph bridging pg 13-14 of the specification, which states: "Following recombination after introduction of the plasmid 14 into the host cells 11, three cell types may be present. Cell type 17 represents a hemizygote containing the integrated human genetic reference sequence 16 and the antibiotic resistance marker 15 flanked by the two mutant LoxP sites 7 and 8. There may also be cells 18 homozygotic for the human genetic reference sequence 16, the antibiotic resistance marker 15 and the two mutant LoxP sites 7 and 8. Finally,

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there will be a population of cells 19 that has not been 5 transformed. [underlining added]” The method of Kuroiwa inherently results in some cells homozygous for the transgene because it is the same method used by applicants – homologous recombination – described by applicants as achieving homozygosity. It is noted that the paragraph bridging pg 13-14 is part of Embodiment 2, which "demonstrates how the invention may be worked to create a di-allelic genetic reference standard" which is equivalent to "diploid" in claim 8 and "a plurality of human genetic reference sequences" in claim 9.

Claim 10 has been included because the human chromosome has been truncated, which is equivalent to "not a functional chromosome."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of what applicants consider a "genetic reference standard" or "genetic reference sequence" (claim 1) are unclear. The specification and the art at the time of filing do not define the phrases. A sequence cloned into a non-mammalian animal cell line is more accurately called a transfected cell line – it is unclear how such a product is a genetic "reference" or a genetic "standard." It cannot be determined what function a sequence must have to be a "genetic reference."

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Claim 6 is indefinite because it cannot be determined which regions of a cell's genome are "dispensable." Pg 12, lines 30-34, teach disruption of the HMGA gene, which is "not strictly required for growth control in DT40 cells. This region of the DT40 genome is thus a suitable target for insertion of the human genetic reference sequence 4. Others may readily be found by the skilled addressee, by reference to the literature (see e.g. Li Y, Strahler JR, Dodgson JB. "Neither HMG-14a nor HMG-17 gene function is required for growth of chicken DT40 cells or maintenance of DNaseI-hypersensitive sites." Nucleic Acids Res. 1997 Jan 15; 25(2):283-8) or sequence databases. However, the claims are not limited to HMGA, HMG-14a or HMG-17. Clarification is required.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday through Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner